

## **REMARKS/ARGUMENTS**

### **DOUBLE PATENTING IN VIEW OF USP 6,120,676**

Several of the claims pending in the present application are rejected on the ground of nonstatutory obviousness-type double patenting in view of various claims of US patent 6,120,676. A terminal disclaimer is provided herewith to obviate this rejection.

### **DOUBLE PATENTING IN VIEW OF USP 6,551,494**

Several of the claims pending in the present application are rejected on the ground of nonstatutory obviousness-type double patenting in view of various claims of US patent 6,551,494. A terminal disclaimer is provided herewith to obviate this rejection.

### **CLAIM REJECTIONS UNDER 35 USC 103**

Claims 45, 46, 50, 51, 53-55, 61, 63-71, 75, 77, 78, 83, and 85-88 are rejected under 35 USC 103(a) as being unpatentable over the English translation of Nakashima et al. (JP 02-326247) in view of Asa et al. (US 4,917,274) and Bratten et al. As now amended, claims 45, 46, 50, 51, 53-55, 61, 63-71, 75, 77, 78, 83, and 85-88 are each allowable, because no combination of Nakashima et al., Asa et al. and Bratten et al. teaches or suggests all of the elements of Applicants' invention. Specifically, each of Applicants' amended claims 45, 46, 50, 51, 53-55, 61, 63-71, 75, 77, 78, 83, and 85-88 now requires that the piercing member and the sensor are mechanically attached together to form an integrated unit that is disconnectable from said analyzer as said integrated unit. This feature provides tremendous advantage especially to self-care diabetics who can

more easily manipulate Applicants' integrated unit instead of fumbling with separate lancet and sensor components, such as the separate lancet 3 and enzyme electrode-containing cap 2 of Nakashima et al.

Nakashima et al. disclose a measurement device main body 1 and lancet 3 that are integrated as stated at page 4, lines 28-29. The measurement device housing 1 of Nakashima et al. is disclosed as having the lancet 3 mounted thereon by holding unit 15 as illustrated at Figure 3 and described at page 6, beginning at line 9, of the specification of Nakasima et al. The housing 1 separately couples thereafter with a cap 2, as also illustrated at Figure 3, by connector 14 and connecting end 41a. This cap 2 is illustrated at Figure 2 as containing the enzyme electrode 4. That is, the lancet 3 and cap 2 are separately couplable to and decouplable from the housing 1 as illustrated at Figures 1-3 and corresponding text of Nakashima et al. Nakashima et al. simply do not disclose nor suggest that the lancet 3 and enzyme electrode 4 form Applicants' advantageous integrated unit that is disconnectable from an analyzer as such, and instead merely disclose the enzyme electrode 4 contained within the cap 2, the cap 2 coupled to the housing 1, and the lancet 3 separately coupled to the housing 1. In addition, none of the other references being relied upon by the Examiner as meeting other elements of Applicants' claims, including Asa et al. and Bratten et al., teach or suggest this feature.

Claims 47-49 and 72-74 are rejected under 35 USC 103(a) as being unpatentable over the English translation of Nakashima et al. (JP 02-326247) in view of Asa et al. (US 4,917,274) and Bratten et al., and in further view of Diebold et al. (US 5,437,999). Claims 47-49 are allowable as being dependent upon claim 45 for the reasons set forth above. Claims 72-74 are allowable as being dependent upon claim 70 for the reasons set forth above. That is, no combination of Nakashima et al., Asa et al., Bratten et al. and Diebold et al.

teaches or suggests all of the elements of Applicants' invention. Specifically, each of Applicants' claims 47-49 and 72-74 now requires that the piercing member and the sensor are mechanically attached together to form an integrated unit that is configured for both lancing and sensing when said piercing member and sensor are attached together as said integrated unit, and also as said integrated unit for being separate from and then coupled with said measuring device for obtaining said electrochemical analysis and analyte concentration determination, and as said integrated unit for separation and disposal from said measuring device after said analysis and determination, in addition to features previously recited.

Claims 62 and 84 are rejected under 35 USC 103(a) as being unpatentable over the English translation of Nakashima et al. (JP 02-326247) in view of Asa et al. (US 4,917,274) and Bratten et al., and in further view of Wojciechowski et al. (US 5,873,990). Claims 62 and 84 are allowable as being dependent respectively upon claims 45 and 70 for the reasons set forth above. That is, no combination of Nakashima et al., Asa et al., Bratten et al. and Wojciechowski et al. teaches or suggests all of the elements of Applicants' invention. Specifically, each of Applicants' claims 62 and 84 now requires that the piercing member and the sensor are mechanically attached together to form an integrated unit that is configured for both lancing and sensing when said piercing member and sensor are attached together as said integrated unit, and also as said integrated unit for being separate from and then coupled with said measuring device for obtaining said electrochemical analysis and analyte concentration determination, and as said integrated unit for separation and disposal from said measuring device after said analysis and determination, in addition to features previously recited.

Claims 45-55, 61, 63-65, 67-78, 83 and 85-88 are rejected under 35 USC 103(a) as being unpatentable over Diebold et al. in view of Smith (US 5,108,889), and

Strauss et al. (US 5,089,320). As now amended, Claims 45-55, 61, 63-65, 67-78, 83 and 85-88 are allowable because no combination of Diebold, Smith and Strauss teaches or suggests all of the elements of Applicants' invention. Specifically, each of Applicants' amended claims 45-55, 61, 63-65, 67-78, 83 and 85-88 now requires that the piercing member and the sensor are mechanically attached together to form an integrated unit that is configured for both lancing and sensing when said piercing member and sensor are attached together as said integrated unit, and also as said integrated unit for being separate from and then coupled with said measuring device for obtaining said electrochemical analysis and analyte concentration determination, and as said integrated unit for separation and disposal from said measuring device after said analysis and determination, in addition to features previously recited.

Claims 56-58, 60, 79, 80 and 82 are rejected under 35 USC 103(a) as being unpatentable over Diebold et al. in view of Smith (US 5,108,889), and Strauss et al. (US 5,089,320), and Anderson (US 5,279,294). Claims 56-58 and 60 are dependent upon claim 45, and claims 79, 80 and 82 are dependent upon claim 70. Thus, each of these claims is allowable for the reasons set forth above. That is, no combination of Diebold et al., Smith, Strauss et al. and Anderson teaches or suggests all of the elements of Applicants' invention. Specifically, each of Applicants' claims 56-58, 60, 79, 80 and 82 now requires that the piercing member and the sensor are mechanically attached together to form an integrated unit that is configured for both lancing and sensing when said piercing member and sensor are attached together as said integrated unit, and also as said integrated unit for being separate from and then coupled with said measuring device for obtaining said electrochemical analysis and analyte concentration determination, and as said integrated unit for separation and disposal from said measuring device after said analysis and determination, in addition to features previously recited. Clearly, Diebold does not teach or suggest any of these

features, as column 12, line 39 merely mentions use of a lancing device to obtain a drop of blood from a patient and discloses no structure nor any connectivity with any other discussed components.

Claims 62 and 84 are rejected under 35 USC 103(a) as being unpatentable over Diebold et al. in view of Smith (US 5,108,889), and Strauss et al. (US 5,089,320), and Wojciechowski et al. (US 5,873,990). Claims 62 and 84 are allowable as being dependent respectively upon claims 45 and 70 for the reasons set forth above. That is, no combination of Diebold et al., Smith, Strauss et al. and Wojciechowski et al. teaches or suggests all of the elements of Applicants' invention. Specifically, each of Applicants' claims 62 and 84 now requires that the piercing member and the sensor are mechanically attached together to form an integrated unit that is configured for both lancing and sensing when said piercing member and sensor are attached together as said integrated unit, and also as said integrated unit for being separate from and then coupled with said measuring device for obtaining said electrochemical analysis and analyte concentration determination, and as said integrated unit for separation and disposal from said measuring device after said analysis and determination, in addition to features previously recited.

#### NEW CLAIMS

New claims 89-109 are allowable for the following reasons. Claims 89-95 are allowable as being based on claim 45. Claims 96-102 are allowable as being based on claim 67. Claims 103-109 are allowable as being based on claim 70. In addition, claims 89-109 are further allowable for following the additional reasons.

Claims 89, 93, 95, 96, 100, 102, 103, 107 and 109 require that the integrated unit is configured for both lancing and sensing when said piercing member and

sensor are attached together as the integrated unit, and this feature is neither taught nor suggested by any combination of the references being relied upon by the Examiner.

Claims 90, 97 and 104 require that the integrated unit is configured for connecting the sensor to the analyzer as the integrated unit, and this feature is neither taught nor suggested by any combination of the references being relied upon by the Examiner.

Claims 91, 98 and 105 require that the working electrode is configured for connecting with an analyzer which provides an electrical potential causing an electrochemical reaction within the fluid that is applied to the measurement zone and performs electrochemical analysis of the fluid and thereby determines the concentration of the analyte, and wherein the integrated unit is configured for connecting to the analyzer for obtaining the electrochemical analysis and analyte concentration determination, and this feature is neither taught nor suggested by any combination of the references being relied upon by the Examiner.

Claims 92, 94, 99, 101, 106, and 108 require that the integrated unit is configured for separating and disposing as an integrated unit from the analyzer after the analysis and determination, and this feature is neither taught nor suggested by any combination of the references being relied upon by the Examiner.

In view of the above, it is respectfully submitted that the application is now in condition for allowance. The Examiner's reconsideration is respectfully requested.

Appl. No. 10/629,348  
Amendment dated July 9, 2007  
Reply to Office Action mailed May 8, 2007

The Commissioner is authorized to charge any deficiencies in fees and credit any overpayment of fees to Deposit Account No. 50-2019. A duplicate page is enclosed.

Respectfully submitted,

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Dated: July 9, 2007

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